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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/023,637

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Michael J. Otto

PHAR 1030 US

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7590

04/12/2006

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EXAMINER

MCINTOSH III, TRAVISS C

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 04/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/023,637

Applicant(s)

OTTO ET AL.

Examiner

Traviss C. McIntosh

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1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-50 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 2, 8, and 9, drawn to compounds of formula I where R is II, classified in class 536, subclass 25.6.
- II. Claims 1, 2, 8, and 9, drawn to compounds of formula I where R is III, classified in class 536, subclass 25.6.
- III. Claims 1, 2, 8, and 9, drawn to compounds of formula I where R is IV, classified in class 536, subclass 26.1.
- IV. Claims 1, 2, 8, and 9, drawn to compounds of formula I where R is V, classified in class 536, subclass 26.1.
- V. Claims 4 and 11, drawn to alcohols, aldehydes, and acids of claim 4, classified in class 549, subclass 200+. It is noted that this group may be subject to further restriction.
- VI. Claims 5 and 12, drawn to various sulfur and phosphorous containing compounds, classified in class 549, subclass 200+. It is noted that this group may be subject to further restriction.
- VII. Claims 6 and 13, drawn to various alkyl containing compounds, classified in class 549, subclass 200+.

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- VIII. Claims 7 and 14, drawn to various diphosphorylated compounds, classified in class 549, subclass 200+. It is noted that this group may be subject to further restriction.
- IX. Claims 15 and 16, drawn to compositions comprising compounds of group I in combination with another antiviral agent, classified in class 514, subclass 44.
- X. Claims 15 and 16, drawn to compositions comprising compounds of group II in combination with another antiviral agent, classified in class 514, subclass 44.
- XI. Claims 15 and 15, drawn to compositions comprising compounds of group III in combination with another antiviral agent, classified in class 514, subclass 48.
- XII. Claims 15 and 16, drawn to compositions comprising compounds of group IV in combination with another antiviral agent, classified in class 514, subclass 48.
- XIII. Claim 18, drawn to compositions comprising compounds of group V in combination with another antiviral agent, classified in class 514, subclass 99+.
- XIV. Claim 19, drawn to compositions comprising compounds of group VI in combination with another antiviral agent, classified in class 514, subclass 99+.
- XV. Claim 20, drawn to compositions comprising compounds of group VII in combination with another antiviral agent, classified in class 514, subclass 99+.
- XVI. Claim 21, drawn to compositions comprising compounds of group VIII in combination with another antiviral agent, classified in class 514, subclass 99+.
- XVII. Claims 22, 23, and 50, drawn to methods of treating a Flaviviridae infection in a host by administering the compounds of group I, classified in class 514, subclass 44.

- XVIII. Claims 22, 23, and 50, drawn to methods of treating a Flaviviridae infection in a host by administering the compounds of group II, classified in class 514, subclass 44.
- XIX. Claims 22, 23, and 50, drawn to methods of treating a Flaviviridae infection in a host by administering the compounds of group III, classified in class 514, subclass 48.
- XX. Claims 22, 23, 24, and 50, drawn to methods of treating a Flaviviridae infection in a host by administering the compounds of group IV, classified in class 514, subclass 48.
- XXI. Claims 25 and 50, drawn to methods of treating a Flaviviridae infection in a host by administering the compounds of group V, classified in class 514, subclass 99+.
- XXII. Claims 26 and 50, drawn to methods of treating a Flaviviridae infection in a host by administering the compounds of group VI, classified in class 514, subclass 99+.
- XXIII. Claims 27 and 50, drawn to methods of treating a Flaviviridae infection in a host by administering the compounds of group VII, classified in class 514, subclass 99+.
- XXIV. Claims 28 and 50, drawn to methods of treating a Flaviviridae infection in a host by administering the compounds of group VIII, classified in class 514, subclass 99+.

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- XXV. Claims 29, 30, and 50, drawn to methods of treating a Flaviviridae infection in a host by administering the compositions of group IX, classified in class 514, subclass 44.
- XXVI. Claims 29, 30, and 50, drawn to methods of treating a Flaviviridae infection in a host by administering the compositions of group X, classified in class 514, subclass 44.
- XXVII. Claims 29, 30, and 50, drawn to methods of treating a Flaviviridae infection in a host by administering the compositions of group XI, classified in class 514, subclass 48.
- XXVIII. Claims 29, 30, 31, and 50, drawn to methods of treating a Flaviviridae infection in a host by administering the compositions of group XII, classified in class 514, subclass 48.
- XXIX. Claims 32 and 50, drawn to methods of treating a Flaviviridae infection in a host by administering the compositions of group XIII, classified in class 514, subclass 99+.
- XXX. Claims 33 and 50, drawn to methods of treating a Flaviviridae infection in a host by administering the compositions of group XIV, classified in class 514, subclass 99+.
- XXXI. Claims 34 and 50, drawn to methods of treating a Flaviviridae infection in a host by administering the compositions of group XV, classified in class 514, subclass 99+.

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XXXII. Claims 35 and 50, drawn to methods of treating a Flaviviridae infection in a host by administering the compositions of group XVI, classified in class 514, subclass 99+.

XXXIII. Claims 36, 37, and 50, drawn to methods of treating abnormal cellular proliferation by administering the compounds of group I, classified in class 514, subclass 44.

XXXIV. Claims 36, 37, and 50, drawn to methods of treating abnormal cellular proliferation by administering the compounds of group II, classified in class 514, subclass 44.

XXXV. Claims 36, 37, and 50, drawn to methods of treating abnormal cellular proliferation by administering the compounds of group III, classified in class 514, subclass 48.

XXXVI. Claims 36, 37, 38, and 50, drawn to methods of treating abnormal cellular proliferation by administering the compounds of group IV, classified in class 514, subclass 46.

XXXVII. Claims 39 and 50, drawn to methods of treating abnormal cellular proliferation by administering the compounds of group V, classified in class 514, subclass 99+.

XXXVIII. Claims 40 and 50, drawn to methods of treating abnormal cellular proliferation by administering the compounds of group VI, classified in class 514, subclass 99+.

- XXXIX. Claims 41 and 50, drawn to methods of treating abnormal cellular proliferation by administering the compounds of group VII, classified in class 514, subclass 99+.
- XL. Claims 42 and 50, drawn to methods of treating abnormal cellular proliferation by administering the compounds of group VIII, classified in class 514, subclass 99+.
- XLI. Claims 43, 44, and 50, drawn to methods of treating abnormal cellular proliferation by administering the compounds of group I in combination or alternation with one or more other effective antiproliferative agents, classified in class 514, subclass 44.
- XLII. Claims 43, 44, and 50, drawn to methods of treating abnormal cellular proliferation by administering the compounds of group II in combination or alternation with one or more other effective antiproliferative agents, classified in class 514, subclass 44.
- XLIII. Claims 43, 44, and 50, drawn to methods of treating abnormal cellular proliferation by administering the compounds of group III in combination or alternation with one or more other effective antiproliferative agents, classified in class 514, subclass 48.
- XLIV. Claims 43, 44, 45, and 50, drawn to methods of treating abnormal cellular proliferation by administering the compounds of group IV in combination or alternation with one or more other effective antiproliferative agents, classified in class 514, subclass 48.

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XLV. Claims 46 and 50, drawn to methods of treating abnormal cellular proliferation by administering the compounds of group V in combination or alternation with one or more other effective antiproliferative agents, classified in class 514, subclass 99+.

XLVI. Claims 47 and 50, drawn to methods of treating abnormal cellular proliferation by administering the compounds of group VI in combination or alternation with one or more other effective antiproliferative agents, classified in class 514, subclass 99+.

XLVII. Claims 48 and 50, drawn to methods of treating abnormal cellular proliferation by administering the compounds of group VII in combination or alternation with one or more other effective antiproliferative agents, classified in class 514, subclass 99+.

XLVIII. Claims 49 and 50, drawn to methods of treating abnormal cellular proliferation by administering the compounds of group VIII in combination or alternation with one or more other effective antiproliferative agents, classified in class 514, subclass 99+.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-VIII are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the groups I-VIII are drawn to patentably distinct

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products. In Group I applicants are claiming compounds comprising 2 sugar moieties wherein one of the modified bases has only C or N moieties in the ring. In Group II applicants are claiming compounds comprising 2 sugar moieties wherein one of the modified bases has C, N, or S in the ring. In Group III applicants are claiming compounds which have 1 sugar molecule linked via an undefined linker (n is not defined in the claim) to a bicyclic structure. In Group IV applicants are claiming compounds which have 1 sugar molecule with a specific linkage to a bicyclic structure. In Group V applicants are claiming non-saccharide containing moieties which are alcohols, aldehydes, or acids. In Group VI applicants are claiming various sulfur and phosphorous containing compounds. In Group VII applicants are claiming various alkyl containing compounds. In Group VIII applicants are claiming various diphosphorylated compounds. Each of groups I-VIII is directed to or involves the use of compounds which are recognized in the art as being distinct from one another because of their diverse chemical structure, their different chemical properties, modes of action, different effects, and reactive conditions. Additionally, the level of skill in the art is not such that one invention would be obvious over the other, i.e., they are patentable over each other. Chemical structures which are similar are presumed to function similarly, while chemical structures which are not similar are not presumed to function similarly. The presumption even for similar chemical structures though is not irrefutable, but may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention. Note that in accordance with the holding of *Application of Papesch*, 50 CCPA 1084, 315 F.2d 381, 137 USPQ 43 (CCPA 1963), and *In re Lalu*, 223 USPQ 1257 (Fed. Cir. 1984), chemical structures are patentably distinct where structures are either not structurally similar, or

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the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure.

Groups I-VIII and IX-XVI are directed to related products. It is noted that the products of Groups I-VIII require only one active agent to be contained therein, and the products of Groups IX-XVI require the compounds of Groups I-VIII and an additional agent. It is noted that a reference anticipating or rendering obvious the compounds/compositions of Groups I-VIII would not necessarily anticipate or render obvious the compositions of Groups IX-XVI. As such, a further search and consideration would be required.

Inventions I-VIII and XVII-XXIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the products can be used in a patentably distinct methods, such as the methods of Groups XXXIII-XL and the methods can be practiced with patentably distinct products, such as using the products of Groups IX-XVI.

Inventions I-VIII and XXV-XXXII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

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product. See MPEP § 806.05(h). In the instant case the products can be used in a patentably distinct methods, such as the methods of Groups XXXIII-XL and the methods can be practiced with patentably distinct products, such as using the products of Groups IX-XVI.

Inventions I-VIII and XXXIII-XL are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the products can be used in a patentably distinct methods, such as the methods of Groups XVII-XXIV.

Inventions I-VIII and XLI-XLVIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the products can be used in a patentably distinct methods, such as the methods of Groups XVII-XXIV.

Inventions IX-XVI and XVII-XXIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

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product. See MPEP § 806.05(h). In the instant case the method can be practiced with patentably distinct products, such as using the products of Groups I-VIII.

Inventions IX-XVI and XXV-XXXII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the method can be practiced with patentably distinct products, such as using the products of Groups I-VIII.

Inventions IX-XVI and XXXIII-XL are not related. The inventions of Groups IX-XVI are drawn to compositions comprising a compound plus an additional antiviral agent, and the methods of Groups XXXIII-XL are drawn to treating abnormal cellular proliferation. A reference anticipating or rendering obvious one group would not necessarily anticipate or render obvious the other groups, thus requiring further search and consideration.

Inventions IX-XVI and XLI-XLVIII are not related. The inventions of Groups IX-XVI are drawn to compositions comprising a compound plus an additional antiviral agent, and the methods of Groups XLI-XLVIII are drawn to treating abnormal cellular proliferation using a composition comprising a combination of a compound and an additional antiproliferative agent. A reference anticipating or rendering obvious one group would not necessarily anticipate or render obvious the other groups, thus requiring further search and consideration.

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Groups XVII-XXIV and XXV-XXXII are directed to related processes. It is noted that the processes of Groups XVII-XXIV require only one active agent to be contained therein, and the processes of Groups XXV-XXXII require multiple agents. It is noted that a reference anticipating or rendering obvious the methods of Groups XVII-XXIV would not necessarily anticipate or render obvious the methods of Groups XXV-XXXII. As such, a further search and consideration would be required.

Inventions XVII-XXIV and XXXIII-XL are not related. The inventions of Groups XVII-XXIV are drawn to methods of treating flavivirus infection, and the methods of Groups XXXIII-XL are drawn to treating abnormal cellular proliferation. A reference anticipating or rendering obvious one group would not necessarily anticipate or render obvious the other groups, thus requiring further search and consideration.

Inventions XVII-XXIV and XLI-XLVIII are not related. The inventions of Groups XVII-XXIV are drawn to methods of treating flavivirus infection, and the methods of Groups XLI-XLVIII are drawn to treating abnormal cellular proliferation with a combination of agents. A reference anticipating or rendering obvious one group would not necessarily anticipate or render obvious the other groups, thus requiring further search and consideration.

Inventions XXV-XXXII and XXXIII-XL are not related. The inventions of Groups XXV-XXXII are drawn to methods of treating flavivirus infection using combination therapy, and the methods of Groups XXXIII-XL are drawn to treating abnormal cellular proliferation. A

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reference anticipating or rendering obvious one group would not necessarily anticipate or render obvious the other groups, thus requiring further search and consideration.

Inventions XXV-XXXII and XLI-XLVIII are not related. The inventions of Groups XVII-XXIV are drawn to methods of treating flavivirus infections using combination therapy, and the methods of Groups XLI-XLVIII are drawn to treating abnormal cellular proliferation with a combination of agents. A reference anticipating or rendering obvious one group would not necessarily anticipate or render obvious the other groups, thus requiring further search and consideration.

Groups XXXIII-XL and XLI-XLVIII are directed to related processes. It is noted that the processes of Groups XXXIII-XL require only one active agent to be contained therein, and the processes of Groups XLI-XLVIII require multiple agents. It is noted that a reference anticipating or rendering obvious the methods of Groups XXXIII-XL would not necessarily anticipate or render obvious the methods of Groups XLI-XLVIII. As such, a further search and consideration would be required.

Because these inventions are distinct for the reasons given above and the search required for one Group is not required for another Group, restriction for examination purposes as indicated is proper. It would indeed impose an undue burden upon the examiner in charge of this application if the instant restriction requirement is not set forth.

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Claims 1-50 are generic to a plurality of disclosed patentably distinct species comprising a plethora of divergent compounds. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. By a single species it is meant a single compound. The compound may be named in any of four ways: 1) according to IUPAC standard, 2) by a pictorial representation of the compound, 3) by setting forth the specific chemical group that each variable of the Markush group represents, or 4) by naming a claim or an example which itself sets forth a single compound.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the

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product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

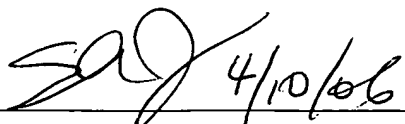
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C. McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Traviss C. McIntosh III
April 7, 2006

Shaojia A. Jiang
Supervisory Patent Examiner
Art Unit 1623

 4/10/06